IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

THOMAS M. STEINBERG, JR., and
AMY M. STEINBERG, et al.,

Plaintiffs,

v. No. CIV 02-950 JC/LFG

CRYOLIFE, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' FIRST MOTION TO COMPEL AND DENYING PLAINTIFFS' SECOND MOTION TO COMPEL

Introduction

THIS MATTER is before the Court on two Motions to Compel filed by Plaintiffs. On January 8, 2003, Plaintiffs filed a Motion to Compel Defendant's Responses with respect to a number of document requests and interrogatories. Motion to Compel #1 was fully briefed as of January 13, 2003. [Doc. 38, 41, and 43.] Plaintiffs' Reply narrowed the remaining discovery issues in dispute. [Doc. 43.] As fully set forth below Plaintiffs' first Motion to Compel will be granted in part and denied in part.

On January 8, 2003, Plaintiffs filed a second Motion to Compel Discovery, which was fully briefed as of January 13, 2003. [Docs. 39, 40, and 44.] The Second Motion to Compel will be summarily denied because Plaintiffs sought to compel production of their "Second Request for

Production, but attached only Defendant's Objections and Responses to Plaintiffs' First Request for Production. Thus, the Court was unable to examine the exact request(s) and response(s) that were in dispute. "A party seeking relief pursuant to Fed.R.Civ.P. 26(c) or 37(a) must attach to the motion a copy of (a) the interrogatory, request for production . . . and (b) response or objection thereto." D.N.M. LR-Civ 37.1. Moreover, it appears that the discovery requests in dispute in the Second Motion to Compel, i.e., document requests for complaints filed for all heart valves and other tissues from 1984 to the present [doc. 40, p. 3.], were, at least to some degree, addressed by the First Motion to Compel. [Doc. 38, Ex. 1, RFP 19, ROG 11.] In any event, the Second Motion to Compel is denied, although some of the same matters raised in that Motion may be resolved in the Court's rulings on the First Motion to Compel.

Background

This is a negligence and products liability case involving the death of Sydney Steinberg, Plaintiffs' five-year old daughter. Sydney suffered from heart problems at birth, and in December 1999, underwent donor heart valve implantation at the University of New Mexico Hospital. The donor heart valve, obtained from a nine-year old donor who died as a result of an accident, was processed by Defendant CryoLife before it was implanted. CryoLife has been involved in the business of human tissue processing since 1984, and over the years, claims to have processed more than 60,000 non-heart valve tissues and more than 16,000 heart valves which are used by surgeons in various reconstructive procedures.

After the implantation procedure, Sydney appeared to improve. Subsequently, her parents relocated to Oregon and Sydney's care was transferred to a heart clinic in that state. While in Oregon, it was discovered that Sydney had a fungal growth on the heart valve. In June 2000, Sydney

underwent a second implant procedure in Oregon, where the prior heart valve was removed and a new one, processed by a different processing company, was implanted. Initially, Sydney improved, but the fungal infection reappeared and she died in December 2000.

Plaintiffs contend that the CryoLife valve was contaminated with arthrographis kalarae when it was provided to Sydney's surgeons for implantation and that this fungal contamination led to Sydney's infection, which over time led to a systemic fungal endocarditis that resulted in her death. Part of Plaintiffs' theory is that CryoLife engaged in improper harvesting, procurement, manufacture and testing of the heart valve before it was implanted. Plaintiffs seek an award of compensatory and punitive damages from CryoLife.

CryoLife asserts that the fungus grown on the heart valve explanted from Sydney in June 2000 was an extremely rare form of fungus and that CryoLife had no reported cases of that type of fungal infection prior to Sydney's death. CryoLife states that it is unaware of any reported cases of fungal endocarditis resulting from arthrographis kalarae. It appears that CryoLife will attempt to defend this case by attempting to show that the contamination could have occurred during the surgical procedure, during the post-surgical hospitalization at UNM Hospital, or through an environmental exposure of Sydney to fungal pores. The same donor who supplied the heart valve to Sydney in New Mexico provided a companion heart valve for another recipient who did not develop any fungal infection or complications.

This discovery dispute concerns a number of issues, including requests for information concerning the FDA's 2002 inspection of CryoLife and a related FDA recall of CryoLife's processed tissue. According to CryoLife, the FDA investigation ensued after reports of three deaths that resulted from patients implanted with orthopedic tissue during knee surgeries in Minnesota. CryoLife

argues that the FDA recall involved only non-cardiac tissues. CryoLife also asserts that only one of the three knee surgery patients received a CryoLife processed tissue, even though the FDA continued its investigation of CryoLife. It appears true that most of the CryoLife tissues found to have had problems involved non-heart valve tissue. In March 22, 2002, however, the Centers for Disease Control and Prevention ("CDC") informed CryoLife that it had received a report of a patient who acquired fungal endocarditis following implantation of an aortic valve and conduit supplied by CryoLife. [Ex. 4.] By May 2002, the CDC notified CryoLife that the total number of infections found to be associated with CryoLife allografts was 21, again almost all of which involved non-cardiac tissues. During the ongoing investigation, the FDA and CDC made recommendations to CryoLife to improve its tissue processing and testing procedures. As of April 12, 2002, CryoLife had not adequately implemented the CDC's recommendations. On June 17, 2002, the FDA issued a warning letter listing deficiencies at CryoLife including matters related to CryoLife's processing of heart valves. CryoLife's June 25, 2002 response did not provide adequate assurance to the CDC that it had addressed the deficiencies. On July 6, 2002, CryoLife acknowledged that the heart valve about which it was notified in March 2002, was the likely source of the serious adverse event, and further that the heart valve was processed and tested by the same methods that CryoLife used in processing non-heart valve tissues. [Ex. 5.]

Legal Standard

Plaintiffs are correct in stating that relevancy during discovery should be construed broadly. However, discovery is not without limits. Rule 26 expressly contemplates the limitation of discovery if the burden or expense of the proposed discovery outweighs its likely benefits, "taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues

at stake in the litigation, and the importance of the proposed discovery in resolving the issues." Fed.R.Civ.P. 26(b)(2)(iii); Burka v. U.S. Dept. of Health and Human Services, 87 F.3d 508, 517 (D.C. Cir. 1996). After consideration of the needs of the parties, the court may, its exercise of discretion, deny discovery completely, limit the conditions, time, place or topics of discovery, or limit the manner in which information is to be revealed. Burka, 87 F.3d at 518.

Thus, the Court is mindful of the need to balance one party's right of discovery with an opposing party's right to be free from intrusive and burdensome discovery. Koch v. Koch Industries, Inc., 203 F.3d 1202, 1238 (10th Cir.), *cert. denied*, 531 U.S. 926, 121 S.Ct. 302 (2000). "Indeed, the 1983 and 1993 Advisory Committee Notes [to Rule 26(b)(2)(iii)] indicate this sub-section was added 'to encourage judges to be more aggressive in identifying and discouraging discovery overuse' and 'to enable the court to keep tighter rein on the extent of discovery.'" Id.

Moreover, due to abusive, unchecked litigation practices that significantly increased the costs of litigation, congested court dockets, and contributed to delay the final disposition of litigation, Congress enacted the Civil Justice Reform Act of 1990 ("CJRA"), 28 U.S.C. § 471, *et seq.* The goals of the CJRA are to expedite the ultimate disposition of litigation and to reduce the costs. These goals are accomplished by close judicial scrutiny of the discovery process, establishment of case management deadlines, and utilization of alternative dispute resolution procedures.

Shortly after the adoption of the CJRA, the Federal Rules of Civil Procedure were modified to dovetail with the CJRA. Indeed, Rule 1 of the revised rules adopts the two-pronged CJRA goals as part of the Rules' purpose. "They [civil rules] shall be construed and administered to secure the just, speedy, and inexpensive determination of every action."

In addition, recent modifications to the federal rules further limit the scope of discovery. For example, Rule 26 previously provided, "Parties may obtain discovery regarding any matter, not privileged . . . ." The revised rule now provides, "Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party . . . ." This rule change signals a narrower scope of permissible discovery than existed before. Therefore, a party is not permitted to plead its allegations in indefinite terms and then conduct broad discovery hoping to benefit from a fishing expedition. Koch, 203 F.3d at 1238; Fed.R.Civ.P. 26, advisory committee notes.

With this balancing process in mind, along with the goal of providing closer judicial scrutiny over the discovery process, the Court now addresses the following discovery disputes that Plaintiffs contend remain at issue: request for production nos. 2, 3, 4, 7, 8, 9, 13, 19, 20, 23, 34, 35, and 36; interrogatory nos. 8, 11 and 16.

Analysis

Request for Production No. 2 requests "all documents, memorandums, e-mails, and/or correspondence associated with the FDA's 2002 inspection of your facility." CryoLife objects with the familiar litany of over broad, not related to any issues in the matter, and not calculated to lead to further admissible evidence. CryoLife argues that the request could call for every document generated subsequent to March 2002 that might be considered "associated with" the inspection. CryoLife also asserts that the request encompasses documents protected by the attorney-client privilege, and that it has now provided all the requested information, except for that information developed in anticipation of litigation or those procedures that are only under consideration and not beyond the developmental stage. CryoLife apparently did not provide a privilege log.

The Court is not inclined to find that incidents occurring after the matter at issue can never be discovered. Indeed, in proving that a product is defective, the Tenth Circuit found evidence admissible at trial of "incidents occurring after the incident at issue, but before the date of trial . . . ." Smith v. Ingersoll-Rand Co., 214 F.3d 1235, 1247-49 (10th Cir. 2000). Thus, those requested documents, not subject to a privilege, should be produced within ten days after entry of this Order. These discovery rulings, however, do not mean that the evidence will be admissible at trial. That question clearly will remain for the Article III Judge to decide.

With respect to CryoLife's privilege objection, it has not provided sufficient information that the matters to be protected related to legal advice. Not all communications to or from counsel are privileged. The question is whether each particular communication at issue was made for the purpose of giving or receiving legal advice. Burton v. R.J. Reynolds Tobacco Co., 177 F.R.D. 491, 496-97 (D. Kan. 1997). To the extent that CryoLife claims that the requested information was created in anticipation of litigation, it should keep in mind that it must demonstrate that the documents were created in anticipation of specific litigation, rather than for the general prospect of future litigation. Id. at 498 ("because litigation is an ever-present possibility in American life, it is more often the case than not that events are documented with the general possibility of litigation in mind;" however, the mere possibility of litigation is not sufficient to establish a privilege).

The Court directs CryoLife to produce to Plaintiffs, within ten days after entry of this Order, a privilege log in accordance with Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973). The log must provide sufficient information to determine whether the communications or documents at issue are entitled to a protection of privilege, e.g., dates of the materials, names of authors and recipients, their

titles or positions, and a precise statement of the grounds for the privilege or work product objection. Sanchez v. KPMG, No. CIV 93-406 (D.N.M. Aug. 5, 1994).

Request for Production No. 3 asks for "all marketing and sales material for cardiac material/heart valves sold by CryoLife from 1993 to the present." CryoLife limited production to the year Sydney's valve was produced and perhaps to some material leading up to the implant procedure. CryoLife further explained that it could not determine the extent of existing advertising prior to 1998 due to a move of its facility in 1998. Plaintiffs argue that evidence of conduct following earlier alleged misconduct is "admissible" to show culpable mental state for purposes of establishing a punitive damage claim.

Based on Plaintiffs' reply, the Court understands the dispute is now narrowed to a request for marketing information subsequent to the implant procedure. The Court disagrees with Plaintiffs' punitive damages argument, particularly in view of the recent United States Supreme Court decision in State Farm Mutual Automobile Insurance Co. v. Campbell, __ S.Ct. __, 2003 WL 1791206 (Apr. 7, 2003). Punitive damages should not be awarded to punish and deter conduct that has no relation to the plaintiff's harm. Id. at *10. The fact that CryoLife marketed a heart valve product subsequent to Sydney's implant surgery has no bearing on the tissue that was processed for and implanted in Sydney. Thus, the requested information is unlikely to lead to the discovery of admissible evidence in this case. Accordingly, the Court will sustain CryoLife's objection as to the request for advertising materials subsequent to Sydney's New Mexico implant procedure. To the extent that CryoLife has not produced materials relating to the advertising of heart valve tissues before that procedure, those documents should be produce for the period of 1997 through December 1999.

Request for Production No. 4 seeks the Design History File ("DHF") for all allograft heart valves produced by CryoLife from 1993 to the present. Defendant states that there is no such document and further that the DHF is a "virtual concept" or a compilation of all standard operating procedures associated with the processing of allograft heart valves or other tissue. Plaintiffs argue that one of CryoLife's previously produced documents refers to a "Device History Record." The Court cannot order a party to produce what it does not have. However, to the extent that a design history file exists, whether identified as a "Device History Record" or a "Design History File," it should be produced.

Request for Production No. 7 asks for "every marketing document provided to the representatives identified in answer to Plaintiffs' Interrogatory No. 7." Interrogatory 7 asked for the identification of sales representatives involved in the sale o f the allograft heart valve "involved in this action." CryoLife responded to the interrogatory with the names of sales representative who placed the order and the technical representative who was responsible for the territory. Defendant responded to the document request by objecting on the grounds that it was over broad with respect to time and scope.

To the extent that it has not already been produced, the Court directs CryoLife to produce those materials provided to the two previously named representatives concerning the marketing or sales of allograft heart valves that those representatives would have had access to at the time Sydney's CryoLife heart valve tissue was marketed and then implanted. For the reasons stated previously, the Court will not direct CryoLife to produce marketing materials that may have been used after the December 1999 implantation procedure.

Request for Production No. 8 seeks all documents identified or related to the responses to Interrogatory Nos. 8 and 9. Interrogatory 8 asks CryoLife to identify "all fungi species ever detected in any stage of the handling of any of CryoLife's products . . . where the fungi species was detected prior to CryoLife's processing the product in any antimicrobial solution or detected after such processing." The request does not provide any limits as to time. Interrogatory 9 requests identification and a list of each fungus species sought to be detected by CryoLife during its processing of allograft heart valves from 1993 to the present.

CryoLife stated that it responded to the interrogatory with specificity based on information reasonably available for its review. However, CryoLife objected on grounds of over breadth, explaining that to provide further specificity would require it to review and produce the entire file on each donor tissue ever received and rejected by CryoLife, in addition to the 75,000 plus tissues that were actually implanted. Plaintiffs contend that CryoLife should not be permitted to take the position that it has never had any reported cases of fungal infection with arthrographis kalarae prior to Sydney's case while refusing to identify which fungi it has isolated from the tissues it processed.

While cognizant of CryoLife's objection that a retrospective review of its records would be unduly burdensome, the Court is not convinced that CryoLife has met its burden in demonstrating undue burden. Defendant has the burden of showing the undue burden or expense and that the burden or expense is unreasonable in light of the benefits to be secured from the discovery. Snowden v. Connaught Lab., Inc., 137 F.R.D. 325, 332 (D. Kan. 1991). The objecting party cannot rely on "generalized objections, but must show specifically how each request is burdensome . . . by submitting affidavits or some detailed explanation as to the nature of the claimed burden." Kutilek v. Gannon, 132 F.R.D. 296, 300 (D. Kan. 1990). Here, CryoLife did not supply any affidavit

statement and did not discuss how the alleged undue burden is disproportionate to the benefits Plaintiffs might gain from the discovery.

Based on Plaintiffs' position in the reply, it appears that the information now sought is somewhat more limited in nature than what was originally in dispute. Thus, to the extent that CryoLife takes the position that it has never had any reported cases of fungal infection with arthrographis kalarae prior to December 1999, the Court proposes to require CryoLife to determine whether it isolated or rejected any tissue samples due to this type of fungus. Any such files located (showing this type of fungus) should be produced for the period of 1993 through December 1999, unless CryoLife produces a verified affidavit by an individual with personal knowledge demonstrating that this type of search would be unduly burdensome as to the number of files, number of hours, and/or number of employees required for the review. The affidavit should be filed with the Court within ten days after entry of this Order, at which point, the Court will re-assess its proposed ruling.

Request for Production No. 9 asks CryoLife to produce every document identified in its response to Interrogatory No. 11. Interrogatory 11 requests CryoLife to identify each and every report or complaint known to CryoLife that any of its products contained a fungus, including how CryoLife received the information, the date of the information, the source of the complaint, the identification of the product, and any response by CryoLife. The request contains no limit as to time, and asks for complaints concerning any type of tissues processed by CryoLife that contained a fungus.

CryoLife objected on grounds that the request is over broad and not reasonably calculated to lead to the discovery of admissible evidence. CryoLife agreed to produce complaint files, redacted in accordance with HIPAA regulations, as to fungal infections associated with any heart valve implanted. The Court generally agrees with CryoLife that the request is too broad as to time, but not

as to scope. Because Plaintiffs' theory concerns alleged improper processing of tissues and there is documentation from the FDA or CDC that CryoLife processed non-cardiac tissues like cardiac tissue, at least as of 1997, the Court will direct CryoLife to produce to Plaintiffs redacted complaint files for all tissues with fungal infections for the period of 1997 to the present. Whether such evidence is admissible at trial is an entirely different question.

Again, if CryoLife provides the Court with a verified affidavit, within ten days of entry of this Order, demonstrating to the Court's satisfaction that the proposed search would be unduly burdensome, the Court will reassess this proposed ruling and may further limit the required production.

Request for Production No. 13 asks for every document identified in CryoLife's response to Interrogatory No. 16. Interrogatory 16 requested the identification of each fungus ever detected in tissue brought in to be processed by CryoLife, including fungi detected before and after processing. Plaintiffs also asked for more specific information regarding the product identification number, CryoLife's response to any detected fungi, whether the product was implanted and, if so, the identity of the person in whom the tissue was implanted.

CryoLife asserted that no tissue was implanted if a fungus was detected after processing. Defendant further stated that it had no compilation of records to examine regarding fungi detected by a culture, but before processing. Thus, it argues that it would have to review over 100,000 files to respond to such an inquiry. It did, however, agree to produce a compilation of the total number of tissues in which fungi were detected from 1999 through the present in spreadsheet form.

Plaintiffs claim that CryoLife's response is contradictory because it admitted elsewhere that there was a compilation for 1996. CryoLife's response regarding the 1996 compilation was that it

was the exception and that the 1996 compilation was already produced. Thus, the Court does not find CryoLife's response to have been contradictory and cannot order CryoLife to produce what it does not have.

CryoLife claims generally that all tissues it received for processing had some form of bacterial or fungal contamination. However, it explains that any companion tissues, found negative for contamination after processing, were provided for implantation, regardless of the testing results prior to processing. As of 1997, CryoLife no longer performed testing before processing. Thus, it is not clear that information about tissue received and processed prior to 1997 would be relevant, since the tissues processed before 1997 would have been handled differently than Sydney's tissue that was implanted in1999. Again, the Court is not convinced that CryoLife satisfied its burden in demonstrating undue burden; however, the Court will limit the production requested. In balancing the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues, along with the potential burden to CryoLife, the Court will limit the information to be produced to the spreadsheet previously offered by CryoLife, but for the years 1997 to the present.

If CryoLife provides the Court with a verified affidavit, within ten days of entry of this Order, demonstrating to the Court's satisfaction that the proposed search would be unduly burdensome, the Court will reassess this proposed ruling and may further limit the required production.

Request for Production No. 19 asks for all files, documents, computer files, reports, etc. for each complaint made to Defendant regarding fungus in any of its products. The request contains no restrictions as to time or type of tissue. CryoLife essentially objects on the same grounds set forth in its response to Interrogatory No. 11 (and to Request for Production No. 54, which has not been

provided by the parties, but which appears to the subject of the Second Request for Production). In its reply, CryoLife refers the Court to its Second Motion to Compel that the Court has dismissed summarily.

The Court finds that this request is somewhat duplicative of Request No. 9/Interrogatory No. 11. Thus, for the reasons stated above, CryoLife is directed to produce the appropriately redacted information for the period 1997 to the present, to the extent that additional responsive exists.

If CryoLife provides the Court with a verified affidavit, within ten days of entry of this Order, demonstrating to the Court's satisfaction that the proposed search would be unduly burdensome, the Court will reassess this proposed ruling and may further limit the required production.

Request for Production Nos. 20 and 23 are similar. Request No. 20 requests all documentation regarding CryoLife's Quality System review from 1993 to the present. Request No. 23 seeks each quality audit, including related documentation, performed from 1993 to the present. CryoLife argues that Plaintiffs failed to limit the inquiry in scope and/or to a reasonable period of time. CryoLife further states that it previously produced its quality manual and the standard operating procedures related to tissue processing that include systems review procedures. Plaintiffs argue in their reply that CryoLife has been unwilling to produce the quality audits themselves even though Plaintiffs may be willing to provide the quality audits that address measures taken to minimize the risk of contamination of heart valves.

The Court agrees that the period of time requested is over broad. The Court is unable to determine, based on arguments before it, what information exists in response to this inquiry and how the inquiry may or may not be over broad in scope. However, the fact that CryoLife apparently processed cardiac and non-cardiac tissue alike beginning in 1997 may make the request for such

information relevant, at least for purposes of discovery. Thus, the Court directs CryoLife to produce the quality audits, in question, for the period of 1997 through 1999.

Request for Production No. 34 asks for duplicates of all donor criteria and processing criteria in effect from 1993 to the present. CryoLife makes the usual objections, and states that it will produce, under a Protective Order, the standard operating procedures that it deems responsive to the request. CryoLife further asserts that the entire donor criteria and processing instructions have been produced previously. Plaintiffs argue that they sought information about "procurement training that CryoLife may provide to the organizations that harvest tissue" and that this information has not been produced. To the extent that Plaintiffs read Request No. 34 to ask for procurement training materials, the Court finds the request to be vague and ambiguous since it states nothing about procurement or training. Therefore, no further production by CryoLife is required in response to this request.

Request for Production No. 35 seeks policies and procedures addressing microbial testing, including the procedures addressing when CryoLife will discard harvested tissue, for the period of 1993 to the present. CryoLife makes its usual objections and then states it will produce standard operating procedures that it deems responsive "for the tissue involved." CryoLife further explains that it already produced all SOPs associated with microbial testing and has offered Plaintiffs the opportunity to inspect the results of all microbial testing, that runs into tens of thousands of document pages. Plaintiffs contend that they still seek specific discard criteria used by CryoLife in determining when to discard tissue it has processed.

The Court agrees that the discard criteria was requested and should be produced for cardiac and non-cardiac tissues, but for the more limited period of 1997 through 1999.

Request for Production No. 36 asks for copies of policies and procedures that CryoLife follows to assure that its data regarding the reporting of infection rates is accurate and complete, for the period of 1993 to the present. CryoLife again states it has produced responsive SOP's. Plaintiffs argue that CryoLife has yet to produce materials responsive to Request 36 that actually seeks to determine the bases for CryoLife's representations to the public and health care providers regarding the company's infection rates. The Court concludes that the request is vague and ambiguous in terms of how Plaintiffs now define what information the request seeks. Thus, CryoLife need not provide any further response to this request.

Interrogatory No. 8 asks CryoLife to identify all fungi species ever detected in any stage of the handling of any of CryoLife's products that were detected prior to or after processing. Defendant reserved an objection of over broad and then responded with a list of allograft tissue from pre and post swabs beginning in mid-2002. CryoLife explained that it was not identifying specific yeast until that date. CryoLife explains further in its response brief that it would require a review of more than 75,000 files to determine if any fungus was ever detected in any tissue sample transferred to CryoLife from the time of harvesting to implantation. CryoLife states that all it can do, without such an extensive review, is to provide a list of fungi species types that were identified and reported (which it already provided) and perhaps to produce records of total numbers of fungi identified from 1999 to the present. Plaintiffs claim the interrogatory has not been answered.

Again, the Court is not convinced that CryoLife has established undue burden. Nonetheless, the Court will order a more limited production than originally requested. The Court directs CryoLife to provide the requested information for fungi species detected in tissues for the period of 1997 to the present.

If CryoLife provides the Court with a verified affidavit, within ten days of entry of this Order, demonstrating to the Court's satisfaction that the proposed search would be unduly burdensome, the Court will reassess this proposed ruling and may further limit the required production.

Interrogatory No. 11 asks for each and every report or complaint known to CryoLife that any of its products contained a fungus, including how the information was received, dates of the information, identities of the person making the report, identification of the specific CryoLife product at issue, and any resulting reports or investigations.

CryoLife agreed to provide information related to heart valve fungus complaints but argued that fungus complaints related to other tissues were not substantially similar and, therefore, need not be supplied. In ruling on the related document request no. 9, the Court ordered CryoLife to produce the requested documents for all tissues from 1997 to the present. The Court now requires that CryoLife provide the same type of information in response to this interrogatory, i.e., responsive information concerning all tissues from 1997 to the present.

The Court recognizes that CryoLife objects on grounds that complaints or information concerning the non-cardiac tissues, as well as CryoLife's subsequent processing of those tissues, are not substantially similar to the cardiac tissue at issue here. CryoLife's objections are more appropriately trial objections. In any event, whether other incidents are sufficiently similar to the one at issue depends largely upon the theory of the case. Wheeler v. John Deere Co., 862 F.2d 1404, 1407 (D. Kan. 1988). Here, Plaintiffs' theory, in part, is that CryoLife's defective or improper processing of the tissues resulted in Sydney's lethal infection. As stated previously, there is documentation that CryoLife utilized the same processing methods, beginning in 1997, whether handling cardiac or non-cardiac tissues. Thus, the requests for information, prior and subsequent to

the 1999 implantation procedure, may lead to the discovery of admissible evidence, even if that evidence is ultimately found to be inadmissible at trial.

More specifically, similar complaints about tissues or the processing of those tissues, both before and after the 1999 implant procedure, may have some bearing on questions of causation, existence of defect or dangerousness. Clearly, however, this discovery ruling is not the same as a ruling on trial admissibility. While evidence may be deemed discoverable, that same information may be inadmissible at trial if the circumstances are not sufficiently similar to render it relevant. Ponder v. Warren Tool Corp., 834 F.2d 1553, 1560 (10th Cir. 1987), *cert. denied*, 459 U.S. 862 (1982); Uitts v. General Motors Corp., 58 F.R.D. 450, 452-53 (E.D. Pa. 1972). Courts have advised that such evidence should be carefully examined before being admitted into evidence "as bearing similarities to the circumstances surrounding the [incident] at issue." Caruso v. Coleman Co., 157 F.R.D. 344, 347 (E.D. Pa. 1994).

Notwithstanding the Court's proposed ruling, if CryoLife provides the Court with a verified affidavit, within ten days of entry of this Order, demonstrating to the Court's satisfaction that the proposed search would be unduly burdensome, the Court will reassess its ruling and may further limit the required production.

Interrogatory No. 16 asks CryoLife to list each fungus ever detected in tissue brought in to be processed by CryoLife, including fungus detected both before and after processing. CryoLife objected on grounds that the question was over broad, compound, unduly burdensome and not calculated to lead to the discovery of admissible evidence. CryoLife further states that the requested information could violate privacy standards under the HIPAA. While reserving these objections, CryoLife referred Plaintiffs to its responses to interrogatories 8 and 9. CryoLife further explained

that any tissues that contained fungi following processing were discarded. CryoLife has no compilation of records of tissues that were cultured prior to processing that contained a fungus and would be required to review potentially 100,000 files or more to respond more fully to this inquiry. CryoLife offered to produce a spreadsheet compilation of the total number of tissues in which fungi were detected from 1999 to the present. As indicated previously, Plaintiffs identified a potential discrepancy with one of CryoLife's other responses that referred to a compilation for 1996.

The Court addressed this same or similar inquiry in ruling on Request for Production No. 13. For the reasons stated above, CryoLife should provide the requested information for the years 1997 to present.

If, however, CryoLife provides the Court with a verified affidavit, within ten days of entry of this Order, demonstrating to the Court's satisfaction that the proposed search would be unduly burdensome, the Court will reassess this proposed ruling and may further limit the required production.

Summary

For the reasons stated above, Plaintiffs' First Motion to Compel is granted in part and denied in part. All documents or information that was ordered to be produced should be supplied to Plaintiffs within ten days after entry of this Order. To the extent that CryoLife contends any of the requested information is protected by a privilege or work product doctrine, a privilege log with the pertinent information should be provided to Plaintiffs, also within ten days after entry of this Order. If CryoLife files a verified affidavit within ten days after entry of this Order, as explained *supra*, the Court will re-evaluate its proposed rulings as to those specific discovery requests. The Second Motion to Compel will be summarily denied due to Plaintiffs' failure to adhere to the local rules.

IT IS THEREFORE ORDERED that:

(1) Plaintiffs' First Motion to Compel [doc. 38] is GRANTED in part and DENIED in part; and

(2) Plaintiffs' Second Motion to Compel [doc. 39] is DENIED.

Lorenzo F. Garcia
Chief United States Magistrate Judge